

### **REMARKS/ARGUMENTS**

Claims 1-20 were pending at the time of the mailing of the outstanding Office Action. Claims 17-20 were withdrawn from consideration. By this amendment, claims 1, 2, 4, 8, 9, 17 and 18 have been amended. No claims have been cancelled or added. Support for the amendment of claims 1 and 17 may be found in the specification at paragraph 0068. Support for the amendment of claims 2 and 18 may be found in the specification at paragraphs 35-39 and 44. Amendments to claims 4, 8 and 9 do not require additional support.

In the Office Action of 19 November 2008, the Examiner rejected claims 1-16 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The recitation of “through-pores (macropores)” in claim 1 was considered to render this claim indefinite. Claim 4 was considered to be indefinite due to the recitation of a micropore size that included zero. Under 35 U.S.C. § 102(b), the Examiner rejected claims 1-16 as anticipated by Tennikova et al. (J. High resol. Chromatogr., 2000, 23, 27-38) (hereinafter “Tennikova”) and claims 1-4 and 7-9 as anticipated by Hatch (US Pat. No. 6,238,565) (hereinafter “Hatch”). Under 35 U.S.C. § 103(a), claims 1-4, 8 and 9 were rejected as being unpatentable over Hatch in view of Urthaler et al. (US Pat. Pub. No. 2004/0002081) (hereinafter “Urthaler”), claims 1-6 and 10-16 were rejected as being unpatentable over Hatch in view of Tennikova.

Claim 1 has been amended to eliminate the dual reference to “through-pores (macropores)” in favor of a recitation simply of “macropores.” Claim 4 has been amended to recite that the micropore size ranges from “greater than zero and less than or equal to 100 nm” thereby eliminating the reference to a micropore size of zero. Although they were not subject to a rejection as being indefinite, claims 8 and 9 contained similar recitations and were similarly amended. Withdrawal of the rejections of claims 1-16 under 35 U.S.C. § 112, second paragraph is respectfully requested.

To anticipate a claim, a reference must teach all elements of the claim (MPEP § 2131). Claims 1 and 17 have been amended to recite the selection of a specific macropore size range. Such a selection may be used to purify a target nucleic acid of a specific size. The Applicants respectfully maintain that none of the cited references, Tennikova, Hatch and Urthaler, teach or suggest changing a macro-pore size according to the size of the nucleic acid molecule to be purified. The macro-pore size in Tennikova, Hatch and Urthaler is not changed by a size of nucleic acids.

For example, Tennikova only provides for variation in the thickness of the monolith to adjust the separation of oligonucleotides of 8 to 14 bases. No teaching or suggestion is made by Tennikova of purifying nucleic acids of greater length, nor does Tennikova teach or suggest varying the size of the macropores to purify nucleic acids of various lengths. Therefore, claim 1 patentably distinguishes over Tennikova. Similarly, claims 2-16, which directly or indirectly depend from and contain all the limitations of claim 1, also patentably distinguish over Tennikova. Withdrawal of the rejection of claims 1-16 as anticipated by Tennikova is respectfully requested.

As mentioned above, Hatch also does not teach or suggest a variation in pore size according to the size of the nucleic acid to be purified. Hatch only provides for the separation of nucleic acids with one composition for nucleic acids of 17 base pairs to 3 kilobase pairs (Hatch, Column 8, lines 5-8 and 20-21.)

Additionally, Hatch does not teach a monolith structure made of a glass, a silica or a hybrid material containing an organic material and a glass or a silica. The monolith structure of Hatch employs only an organic polymer, not a hybrid material. A monolith structure of made by only an organic polymer include may include impurities. Such a monolith structure can not be used for purifying nucleic acid. Furthermore, a monolith structure made of only an organic polymer is likely to be soft (softer than the monolith structure of this invention), and it would be impossible to use such a monolith structure for centrifugal separation or under vacuum as with the claimed invention.

It should also be noted that it is alleged that with regard to claims 3 and 7, it was alleged Hatch's disclosure of the presence of small globules in the macropores satisfied the element of these claims that recited the presence of micropores in the macropores. However, Hatch indicates that the resulting pore sizes in the 1-5 micron (1-5 micrometers) range (Hatch, Column 8, lines 13-17). These pores are near the upper range of the pore sizes recited in the claims, rather than the lower ranges, which would be expected for a micropore within a macropore. Therefore, Hatch can not be said to teach or suggest the elements of claims 3 and 7.

Therefore claims 1-4 and 7-9 patentably distinguish over Hatch. Withdrawal of the rejection of these claims under 35 U.S.C. § 102(b) as anticipated by Hatch is respectfully requested.

Claims 1-4, 8, and 9 stand rejected under 35 U.S.C. § 103(a) as obvious over Hatch in view of Urthaler. To establish a prima facie case of obviousness, three requirements must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. There must also be a reasonable expectation of success and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.) As discussed above, neither Hatch nor Urthaler teach or suggest changing the size of the macro-pores in the monolith according to the size of the nucleic acid molecule to be purified. Neither would one of ordinary skill in the art arrive at such an invention by combining the teachings of Hatch and Urthaler. Therefore, claims 1-4, 8, and 9 patentably distinguish over Hatch and Urthaler. Withdrawal of the rejection of these claims under 35 U.S.C. § 103(a) is respectfully requested.

Claims 1-6 and 10-16 were rejected under 35 U.S.C. § 103(a) as obvious over Hatch in view of Tennikova. As also discussed above, neither Hatch nor Tennikova teach or suggest changing the size of the macro-pores in the monolith according to the

size of the nucleic acid molecule to be purified. Neither would one of ordinary skill in the art arrive at such an invention by combining the teachings of Hatch and Tennikova. Therefore, claims 1-6, and 10-16 patentably distinguish over Hatch and Tennikova. Withdrawal of the rejection of these claims under 35 U.S.C. § 103(a) is respectfully respected.

Accordingly, the Applicants maintain that the claims patentably distinguish over the prior art and are in condition for allowance. The issuance of a Notice of Allowance is earnestly solicited.

The outstanding Office Action was mailed on 19 November 2008. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. Therefore, a petition for a three month extension of time is hereby made with this response. No other fees are believed to be due. The Commissioner is authorized to charge any fee or to credit any overpayment associated with the filing of this paper to Deposit Account 15-0450.

Respectfully submitted,

/John J. Cunniff/

John J. Cunniff  
Reg. No 42,451  
Hahn Loeser + Parks LLP  
One GOJO Plaza  
Suite 300  
Akron, OH 44311

Attorney for Applicants